REMARKS

Applicant thanks Examiner Shay for his time and attention, as well as his helpful suggestions regarding this matter, during the March 31, 2009 Examiner's Interview with Applicant's undersigned attorney. Applicant further acknowledges, with thanks, receipt of the Interview Summary. As indicated in the Summary, during the interview the Fischer and Kittrell references and possible claim amendments were discussed. As also indicated in the Interview Summary, the Examiner indicated that an amendment to recite the operation of selecting a fiber with a pre-determined index profile would distinguish at least over the Kittrell reference.

As a preliminary matter, the Examiner designated the outstanding action as a Final Action notwithstanding that the outstanding action is the first action immediately subsequent to the filing of an RCE. Specifically, the Examiner stated:

> All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.1 14 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.1 14. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.1 14. See MPEP § 706.07(b). (Emphasis in the original, Final Action, page 8)

Applicant respectfully disagrees with the Examiner contentions that the pending claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114..

Specifically, in its November 24, 2008, Amendment in Reply to Final Action of May 22, 2008, applicant amended the claim to, in part, "passing the electromagnetic radiation through a graded index optical fiber, the graded index optical fiber having ~~dimensions~~ a graded index core profile and a length selected to modify the electromagnetic radiation." Thus, applicant replaced the recitation "the graded index optical fiber having dimensions ..." to "the graded index optical fiber having a graded index core profile and a length selected ...". Clearly, the recited feature "the graded index optical fiber having dimensions ..." is different in terms of the terminology used and in the scope of protection sought, from the recited feature "the graded index optical fiber having a graded index core profile and a length selected ...". Similar amendments were made with respect to independent claims 17, 26 and 35. On that basis alone, it cannot be said that the pending claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114.

Applicant therefore respectfully requests that the Examiner withdraw the finality of the outstanding action.

Turning now to the Examiner rejections and objections, the Examiner maintained his objection to the drawings under 37 CFR 1.83(a) on the ground that the drawings must show every feature of the invention specified in the claims. To expedite prosecution of the above-identified application, applicant cancelled, without prejudice, claims 48-51 reciting features pertaining to the irrigation of the tissue with an aqueous solution.

The Examiner rejected claims 1, 2, 7-12, 15-17, 20-22, 24-27, 30, 33-38, 43 and 46-51 under U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,304,173 to Kittrell et al.

Also, the Examiner rejected claims 1-3, 6-11, 15-18, 20, 21, 23-28, 30, 33-36, 38, 40, 41, 43 and 46 and 47 under U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,835,647 to Fischer et al.

Additionally, the Examiner rejected claims 1-3, 6-12, 15-18, 20-28, 30, 33-38, 40, 41, 43 and 46-51 under 35 U.S.C. §103(a) as being unpatentable over Fischer in combination with Kittrell.

Furthermore, the Examiner rejected claims 5 and 39 under 35 U.S.C. §103(a) as being unpatentable over Fischer in combination with U.S. Patent No. 6,199,554 to Mann et al. The Examiner also rejected claims 5 and 39 under 35 U.S.C. §103(a) as being unpatentable over Fischer in combination with Kittrell, and further in combination with Mann.

The Examiner rejected claims 4, 19, 29 and 42 under 35 U.S.C. §103(a) as being unpatentable over Fischer in combination with U.S. Patent No. 5,951,543 to Brauer, and further rejected claims 4, 19, 29 and 42 under 35 U.S.C. §103(a) as being unpatentable over Fischer in combination with Kittrell, and further in combination with Brauer.

As discussed with the Examiner during the March 31, 2009 Examiner Interview, applicant amended independent claim 1 to clarify that applicant's method includes the operation of selecting a graded index optical fiber having a pre-determined graded index profile and a pre-determined length. Applicant further amended independent claim 1 to recite coupling the electromagnetic produced to the selected optical fiber to control a resultant intensity distribution by modifying the coupled electromagnetic radiation based on the pre-determined profile and pre-determined length of the fiber. Support for these clarifications is provided throughout the application, including, for example, at paragraphs 18-19 on pages 1 and 2 and at paragraphs 24 an 27 on page 2 of the published application (PG Patent Publication No. 2004/0199148). Applicant similarly amended independent claims 17, 26 and 35. Applicant also amended claim 15 to correct a typographical error.

Applicant's amended independent claim 1 thus recites "selecting a graded index optical fiber having a pre-determined graded index profile and a pre-determined length selected to modify the electromagnetic radiation to a modified output electromagnetic radiation having an intensity distribution including one of a substantially Gaussian intensity distribution, a substantially bell curve shaped intensity distribution, a substantially parabolic intensity distribution and a substantially Lorentzian intensity distribution; coupling the electromagnetic radiation to the selected graded index optical fiber to control a resultant intensity distribution to be applied to the human body by modifying the coupled electromagnetic radiation based on the pre-determined graded index and the pre-determined length of the optical fiber." As explained in the published application:

> **[0019] The graded index design of the core 102 causes the electromagnetic radiation entering the GRIN fiber 100 to be constantly refracted towards the center of the core. Due to the propagation characteristics of electromagnetic radiation along the GRIN fiber 100 the output radiation emitted from the GRIN fiber 100 may be modified such that the intensity distribution of the radiation is increased around the center when viewed cross-sectionally. For example, the output radiation may have an about Gaussian or Lorentzian intensity distribution, or more towards a Gaussian or Lorentzian distribution than that of the input beam. Other cross sectional distributions may be produced, such as a bell curve distribution, or a distribution more towards a bell curve than that of the input beam. The level of intensity of the radiation may depend upon, among other factors, the length of the GRIN fiber 100. A substantially Gaussian or Lorentzian intensity may be achieved provided that the length of the GRIN fiber 100 is above a certain threshold. In other embodiments, less than this threshold length may be used to move the intensity distribution towards the Gaussian or Lorentzian. The GRIN fiber 100 may be manufactured and designed using known methods. (PG Patent Publication No. 2004/0199148, page 2, paragraph 19)**

And:

> **[0027] According to one embodiment of the present invention the GRIN optical fiber 212 may have a refractive index profile graded parabolically from a value of approximately 1.475 at the core center to a value of approximately 1.447 at the core's edge and the step index optical fiber 210 may have a refractive index value of approximately 1.447. However, other GRIN optical fibers 212 having different index profiles and/or values and other step index optical fibers 210 having a different refractive index may be selected. (PG Patent Publication No. 2004/0199148, page 2, paragraph 27)**

Thus, by selecting an optical fiber having a pre-determined (or pre-selected) graded profile and/or a pre-determined length, the resultant output intensity distribution of the output laser beam can be controlled by having the coupled input radiation modified by the pre-determined profile and/or pre-determined length of the selected optical fiber.

In contrast, none of the cited references relied upon by the Examiner discloses or suggests at least the features of "selecting a graded index optical fiber having a pre-determined

graded index profile and a pre-determined length selected to modify the electromagnetic radiation to a modified output electromagnetic radiation having an intensity distribution including one of a substantially Gaussian intensity distribution, a substantially bell curve shaped intensity distribution, a substantially parabolic intensity distribution and a substantially Lorentzian intensity distribution; coupling the electromagnetic radiation to the selected graded index optical fiber to control a resultant intensity distribution to be applied to the human body by modifying the coupled electromagnetic radiation based on the pre-determined graded index and the pre-determined length of the optical fiber," as required by applicant's amended independent claim 1.

Kittrell describes optical fibers within a catheter that direct laser radiation for medical applications that include diagnosis and removal of arterial or vascular obstructions (Kittrell, col. 1, lines 16-20). Kittrell explains that in some embodiments the optical fiber may be a graded index optical fiber:

> **Alternate embodiments of optical fibers 20 include any light conduit. The optical fiber described previously has a core 22 which carries the optical radiation, a cladding 24 of lower index of refraction which confines the radiation, and a jacket or buffer 26 which protects and strengthens the optical fibers 20, FIG. 2. Alternate embodiments include optical fibers 20 without buffer 26, and without buffer 26 or cladding 24. (In the case of core only the surrounding air or gas functions as lower index cladding.) Graded index optical fibers may also be used. The core 22 need not be solid; a fluid filled tube may also be considered an optical fiber 20. A gas or air filled hollow waveguide tube may also be used, and may be made of metal, glass or plastic, with an optional reflective coating inside. Various numbers of optical fibers may be used. In the preferred embodiment, nineteen optical fibers 20 form a symmetric hexagonal close packing array as shown in FIG. 1A. This is likewise true for the seven optical fiber 20 configuration shown in FIG. 3. The sequence for larger numbers of optical fibers is thirty-seven, sixty-one, etc., to form, hexagonal close packing. The optical fibers need not all be the same size or type in a laser catheter. (Kittrell, emphasis added, col. 13, lines 1-23)**

While Kittrell disclosed that graded index optical fiber may be used, at no point does Kittrell describe selecting an optical fiber having a specific pre-determined profile and/or a pre-determined length, and Kittrell certainly does not describe that the pre-determined profile and/or pre-determined length of the fiber modify input radiation to a modified electromagnetic radiation having an intensity distribution including one of a substantially Gaussian intensity distribution, a substantially bell curve shaped intensity distribution, a substantially parabolic intensity distribution and/or a substantially Lorentzian intensity distribution. Kittrell also does not describe controlling the resultant intensity distribution by modifying radiation coupled to the selected optical fiber having the pre-determined profile and/or length.

Accordingly, Kittrell fails to disclose or suggest at least the features of "selecting a graded index optical fiber having a pre-determined graded index profile and a pre-determined length selected to modify the electromagnetic radiation to a modified output electromagnetic radiation having an intensity distribution including one of a substantially Gaussian intensity distribution, a substantially bell curve shaped intensity distribution, a substantially parabolic intensity distribution and a substantially Lorentzian intensity distribution; coupling the electromagnetic radiation to the selected graded index optical fiber to control a resultant intensity distribution to be applied to the human body by modifying the coupled electromagnetic radiation based on the pre-determined graded index and the pre-determined length of the optical fiber," as required by applicant's amended independent claim 1.

Fischer describes a device for generating a laser beam having a homogenized cross section (Abstract). Particularly, Fischer's device includes a solid state laser and a transmission fiber 2 to carry the generated radiation of the laser. The transmission fiber is terminated in a broken surface 4 that is followed by an end piece 5 such as a quartz rod:

> **The radiation exiting therefrom enters a transmission fiber 2. This is a fiber having a length of at least 0.2 m and an external diameter of between 50 and 1000 µm. The transmission fiber 2 consists, for example, of ZrF_4 or of another material which is transparent to the wavelength emitted by the solid-state laser 1. This wavelength is between 2 and 3 µm in the stated substances.**
>
> **At the free end 3, the transmission fiber 2 terminate in a broken surface 4 and is followed at a spacing of between 0 and 20 mm by an end piece 5, for example, a quartz rod having a length of between 5 and 50 mm.**
>
> **The free end of the transmission fiber 2 and the end piece 5 are jointly held in a metal sleeve 6 by means of, for example, an adhesive 7.**
>
> **The end faces 8 of the end piece 5 are formed plane, for example, by polishing. They extend perpendicularly to the longitudinal axis of the end piece 5.**
>
> **The laser radiation generated by this device is emitted divergently and exhibits a rotationally symmetrical radiation distribution which is mode-homogenized. For example, the intensity distribution over the cross section, which is indicated by way of an example in the drawing, can be a Gaussian distribution, a super Gaussian, a parabolic or also a ring-shaped distribution. This depends, inter alia on the length of the transmission fiber, on the entrance angle into the transmission fiber and also on the flexure of the transmission fiber. (Fischer, col. 3, line 45 to col. 4, line 4)**

Thus, as is made clear by Fischer, a Gaussian distribution (or other forms of distributions) of the output radiation is generated by the resultant interaction of the fiber 2 with the end piece 5 of Fischer's device. Indeed, as shown in FIG. 1, the resultant Gaussian intensity

distribution is formed at the end face 8 of the end piece 5. Fischer's transmission fiber does not by itself modify the radiation passing through it to a particular intensity distribution such as a Gaussian distribution. Furthermore, there is no indication anywhere in Fischer that a fiber with a pre-determined graded profile and/or pre-determined length is selected, much less selected to control the intensity distribution of a resultant output laser beam.

Accordingly, Fischer also fails to disclose or suggest at least the features of "selecting a graded index optical fiber having a pre-determined graded index profile and a pre-determined length selected to modify the electromagnetic radiation to a modified output electromagnetic radiation having an intensity distribution including one of a substantially Gaussian intensity distribution, a substantially bell curve shaped intensity distribution, a substantially parabolic intensity distribution and a substantially Lorentzian intensity distribution; coupling the electromagnetic radiation to the selected graded index optical fiber to control a resultant intensity distribution to be applied to the human body by modifying the coupled electromagnetic radiation based on the pre-determined graded index and the pre-determined length of the optical fiber," as required by applicant's amended independent claim 1.

Because none of the cited references discloses or suggests, alone or in combination, at least the features of "selecting a graded index optical fiber having a pre-determined graded index profile and a pre-determined length selected to modify the electromagnetic radiation to a modified output electromagnetic radiation having an intensity distribution including one of a substantially Gaussian intensity distribution, a substantially bell curve shaped intensity distribution, a substantially parabolic intensity distribution and a substantially Lorentzian intensity distribution; coupling the electromagnetic radiation to the selected graded index optical fiber to control a resultant intensity distribution to be applied to the human body by modifying the coupled electromagnetic radiation based on the pre-determined graded index and the pre-determined length of the optical fiber," applicant's independent claim 1, and the claims depending from it, are therefore patentable over the cited prior art references.

Applicant's independent claims 17, 26 and 35 recite "selecting an optical fiber, the optical fiber having a pre-determined graded index profile and a pre-determined length selected to modify the laser beam to a modified laser beam having an intensity distribution corresponding substantially to a Gaussian intensity distribution; coupling the laser beam to the selected graded index optical fiber to control a resultant intensity distribution to be applied to the human body by modifying the coupled laser beam based on the pre-determined graded index and the pre-determined length of the optical fiber," or similar language. For reasons similar to those

provided with respect to independent claim 1, at least these features are not disclosed by the cited prior art references. Applicant's independent claims 17, 26 and 35, and the respective claims depending from them, are therefore patentable over the cited art.

CONCLUSION

It is believed that all of the pending claims have been addressed in this paper. However, failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

On the basis of the foregoing amendments, applicant respectfully submits that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

The Commissioner is hereby authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 35678-604C01US.

Respectfully submitted,

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Ido Rabinovitch, Reg. No. L0080

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
One Financial Center
Boston, Massachusetts 02111
Customer No. 30623
Tel.: 617/542-6000
Fax: 617/542-2241